

REMARKS/ARGUMENTS

Applicant responds herein to the Office Action dated June 11, 2008.

Claims 1-8, 10-31 and 33-36 are pending in the instant application and stand rejected. In the Final Office Action, the Examiner rejected the claims as follows:

- 1) Claims 1-8, 10-12 and 33-36 were rejected under 35 U.S.C. §103(a) as being unpatentable over Oberlander (6,554,852) in view of Fenton, Jr. (6,056,751).
- 2) Claims 1-8 and 10-19 were rejected under 35 U.S.C. §103(a) as being unpatentable over Oberlander (6,554,852) in view of Fenton, Jr. (6,056,751) in view of Sasaki *et al.* (5,735,183).
- 3) Claims 1-8 and 10-20 were rejected under 35 U.S.C. §103(a) as being unpatentable over Oberlander (6,554,852) in view of Fenton, Jr. (6,056,751) in view of Sasaki *et al.* (5,735,183) in view of Runck *et al.* (3,832,139).
- 4) Claims 1-8 and 10-19 and 21 were rejected under 35 U.S.C. §103(a) as being unpatentable over Oberlander (6,554,852) in view of Fenton, Jr. (6,056,751) in view of Sasaki *et al.* (5,735,183) in view of Runck *et al.* (3,832,139).
- 5) Claims 1-8 and 10-12 and 22-30 were rejected under 35 U.S.C. §103(a) as being unpatentable over Oberlander (6,554,852) in view of Fenton, Jr. (6,056,751) in view of Bone (3,875,648).
- 6) Claim 31 was rejected under 35 USC §103(a) as being unpatentable over Oberlander (6,554,852) in view of Fenton, Jr. (6,056,751) in view of Bone (3,875,648).

The rejections are respectfully traversed for the following reasons.

Independent claim 1 has been amended (and independent claim 36 has been similarly amended) to specify that:

“...the rigid fixing means adapted to externally extend across an incision of the incised sternum between first and second anchor means and being removably tightly held by the first and second anchor means as a non-attached member separate from the first and second anchor means, the rigid fixing means adapted to maintain the left half of the sternum and the right half of the sternum in relative position for reapproximation...”

The amendments to the claims clarify existing structural elements and relative placements and do not raise new issues. Entry thereof is appropriate and is respectfully requested.

In response to the rejections it is submitted that independent claims 1 and 36 (and claims dependent on claim 1) have been primarily rejected on the basis of a combination of the Oberlander reference in view of Fenton, Jr. However, neither of such references is relevant to the presently claimed invention.

The Oberlander and Fenton, Jr. references do not disclose or teach any body parts separated by an incision such as the incised sternum as presently claimed. The Oberlander and Fenton, Jr. references accordingly do not disclose, teach or even suggest a closure system for any body part for reconnecting or reapproximating body parts separated with an incision, including the sternal closure, as claimed herein. The Oberlander and Fenton, Jr. references do not disclose, teach or suggest any fastening elements which, “externally extend across an incision” as presently claimed.

Instead, the Oberlander and Fenton, Jr. references both disclose either the suturing or stapling of tissue, which has separated from a bone substrate, to the bone substrate. The suturing or stapling, connecting the tissue to the bone in both Oberlander and Fenton, Jr., is effected in a vertical direction and not **across an incision**, as presently claimed. Figures 10, 11, 13 and 14 of Oberlander and Figure 10 of Fenton, Jr. all show a layer of tissue being disposed on a bone substrate with the tissue being vertically stapled or sutured to the bone substrate. The suture of Oberlander and the staple of Fenton, Jr. do not “externally extend across” the interface between tissue and bone. Even if the interface between tissue and bone were to be construed as an “incision” the suture of Oberlander and the staple of Fenton, extend “through” the bone and tissue at the respective separation interfaces and not “externally across an incision”, as required by the claims.

Independent claim 1 has been amended (with independent claim 36 having been similarly amended) to specify that “the rigid fixing means...being removably tightly held by the first and second anchor means as a **non-attached member separate** from the first and second anchor means...”. Claim 10 specifies that the legs are slightly curved for tight disposing in the inner axial passages of the anchor means. The rigid fastening means or fastener is clearly claimed as not being attached to the anchors and it remains as a separate member. In contrast, both Oberlander and Fenton, Jr. absolutely require that the suture or staple be integrated with the anchors for basic operability in order to tie the tissue to the bone in a vertical direction for

attachment. To effect this, Oberlander simply integrates suture 30 with the anchors and states that, "The suture can be molded directly into the anchor...or otherwise fixed to the anchor...". Fenton, Jr. requires that the band 60, in Figure 10, be fused to the bone anchor 12 *in situ*, stating that "...a bondable band 60 is fused to the bone anchors so as to define a tissue capture region..." (col. 6, lines 23-24). Claim 1 of Fenton, Jr., in defining Fenton, Jr.'s invention, specifically requires that the bone anchor and joiner are fused. The fasteners, as claimed herein, are separate and are readily extracted without trauma, if necessary. The fastening elements of Oberlander and Fenton, Jr. are integral or bonded to the anchors and cannot be extracted. There is no requirement for extractability in Oberlander or Fenton, Jr., for separation of tissue from bone, analogous to re-opening of a sternum as in the present claims.

Neither Oberlander nor Fenton, Jr. disclose fixation assemblies which meet the requirements of the present claims, as described above, whether taken alone or in combination with any of the other cited references. In addition, as also described above, the Oberlander and Fenton, Jr. assemblies cannot even be modified to provide the closure system of independent claims 1 and 36, without totally obviating their respective inventions. Claims 1 and 36 are accordingly patentable over the cited prior art, as are the claims dependent on claim 1, for at least the reasons given with respect to claims 1 and 36.

Accordingly, the Examiner is respectfully requested to reconsider the application, allow the claims as amended and pass this case to issue.

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Respectfully submitted,



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